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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,393	12/18/2000	Manfred Weigele	395D US	3200

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,393

Applicant(s)

WEIGELE ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 35-39 is/are rejected.
- 7) ☒ Claim(s) 19-34 and 40-46 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 19-34 and 40-46 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Thus, all claims which depend on e.g. claim 18 are improperly multiply dependent. See MPEP § 608.01(n) ("a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly."). Accordingly, the claims 19-34 and 40-46 have not been further treated on the merits.

Election/Restrictions

The election of species requirement is withdrawn.

Information Disclosure Statement

The IDS of 9/14/01 has been processed. However, that of 1/8/02 was amended. Applicants did not file references for 7 of the 8 items, just the Beilstein database printouts, and so that is what was all that could be cited.

Specification

The abstract is objected to. The critical feature of R^B comprising a P containing moiety must be included.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Charubala.

Compounds 5, 6, 9, 14 anticipate. In claim 1, proviso (A) is met by either branch, Proviso (B) does not apply because its condition is not met and proviso (C) is met by branch (1). In addition, 29, 30, 32 and 33 anticipate because proviso (C) is met by branch (3). The cyano-alkoxy is not a prohibited value for R^J.

Claims 1-3, 10-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Brush et al.

See the structure formed in figure 1B; proviso (C) is met by branch (1) and (3) both.

Claims 1-3, 10-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tate.

Compounds 1 and 9 in figure 1 anticipate. In claim 1, proviso (A) is met by either branch, Proviso (B) does not apply because its condition is not met and proviso (C) is met by branch (1) and by branch (3), since the heteroaliphatic-oxy is not a prohibited value for R^J.

Claims 1-3, 6-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wada.

In scheme 2, see 7a, 10b, 10c, 9a, 13b, which anticipate claims 6-9, as these claims have no relevant provisos. In addition, 7a, 8a and 9a anticipate claims 1-3, 10-15, 18 because proviso (C) is met by branch (3). The cyano-ethoxy (CE) is not a prohibited value for R^J.

Claims 1-3, 10-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Filippov.

For 2, 5 and 6, proviso (C) is met by branch (3). The cyano-ethoxy (OCE) and the cycloalkyloxy are both not a prohibited value for R^J. Moreover, for (1) and (2) branch (1) of C is also met. For Proviso (B), the condition is met for 2, 5 and 6, even if a very broad definition of "derivative" is used (see point 10 below), because, although there is a heteroatom attached to the cycloalkyl ring, there is no halogen. Compound (1) satisfies the proviso because its R^B is none of those choices.

Claims 1-3, 6-15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo.

See compound 4b, which because of the sulfur meets branch (3) of proviso C) and because of the S anticipates claims such as 6.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18, 35-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-174 of

copending Application No. 09/740653. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the two cases are broadly overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-18, 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The term "aliphatic" has been rendered indefinite by the specification. Aliphatic means lacking in rings. But page 22, line 18 says that aliphatic includes things with cycles, and cycloalkyl is listed; others appear at page 22, lines 20-21 and 28-30. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). Since applicants have obliterated the essential requirement for aliphatic, there is no way of knowing what the term means.
2. Further the phrase "aliphatic, heteroaliphatic" appears to be redundant, since the former completely embraces the latter.
3. Likewise, the term "substituted or unsubstituted aliphatic" (e.g. at page 100, line 24) makes no sense, as aliphatic already permits substituents.

4. Similarly, it is unclear what "heteroaliphatic" means either. It appears to be any moiety which has an atom other than C and H. Is that what is intended?
5. The text at page 99 lines 16-17 "wherein ... unsubstituted" is of unclear purpose. This appears to repeat what the specification already says, and hence, if it were to be removed, the scope of the claim would be the same. Hence, its function is unknown.
6. It is unknown what "terminating in a cyano" at page 99, line 24 requires. Cyano is self terminating, as it can take no further substituent. Thus, would CH(CN)Ethyl be terminated with CN, and the ethyl is just a substituent on the cyano-methyl? Or is it not terminated, as the ethyl continues the chain?
7. Page 99, line 30 has "e.g." which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
8. Further, it is unclear how one would get an ether out of what is set forth. If the alkyl were interrupted by an oxygen, then one would obtain an ether, but not substituted. Likewise for alcohol. Substitution with oxygen would give an aldehyde or ketone, not an ether or alcohol.
9. It is unclear how the last three lines of page 99 operate. Does the "derivative of" operate only on the cycloalkyl, or on the entire list? In other words, does R^B have to be other than a heteroatom & halogen substituted alkyl, or other than an alkyl? The claim could be read either way.
10. Moreover, it is not clear how the "derivative" is supposed to operate. Does this require that R^B be other than the substituted cycloalkyl, or does it require that R^B not have a substituted cycloalkyl anywhere at all in it? Thus, if R^B were -(CH₂)_n-

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substituted cycloalkyl, that is clearly a substituted cycloalkyl if $n = 0$, but does it count as a substituted cycloalkyl if $n = 1$? The examiner assumes that $n=1$ is not intended to be excluded.

11. Page 100, line 5, has an unmatched left parenthesis.
12. The arylamino of line 5 appears to be already included in the NR^kR^k term, if R^k is permitted to be H (which is not clear).
13. Likewise, line 6 has an unmatched right parenthesis.
14. The use of the plural "atoms" at page 100 line 8 does not make sense, as there is just the one N atom which connects the two variables.
15. The amino acid of page 100 line 5 is impossible. This is a molecule, but the variable must be a moiety. Thus, it is unclear whether this is bound via an ordinary carbon, the N or the carboxyl.
16. Further, which amino acid ---any molecule containing an amino group and an acid function? Would the language include carbamic acid, or aminobenzenesulfonic acid?
17. At page 100, line 29, Y links R1 and either carbonyl or sulfonyl. But line 21 refers to linking it to P. Does this mean that on line 29, last two choices, it cannot be a bond?
18. Page 100, line 33 mentions a variable M' but does not define it.
19. Page 100, lines 33-34 is unclear. How could a methylene group be unsaturated? By its very nature, methylene is saturated.
20. Also, what does the "electronically" mean? Is this a process step --- i.e. does this mean electrolytically? If not, how would the claim scope differ if the term were removed?
21. Claims 6-9 have the variables R1, R2, R6, G, K, M, Y, x and M_Y undefined.

22. Claim 3 has the variable R6 undefined.
23. Claims 10-11 have the variables R1, R2, G, K, M, Y, x and M_Y undefined.
24. The term "or a pharmaceutically acceptable derivative thereof" (e.g. claim 1, line 1) is of unknown scope. What is a derivative? What level of change can be made in the compounds and it still be a derivative? Can the P be removed?
25. Claim 14 does not end with a period.
26. Page 114, line 5 has a stray bracket.
27. The page 111, line 21 and 113, line 1, page 114, line 13 reference to R^B does not make sense; presumably, R^D was intended.
28. No independent definition is given for R^k. For whatever choice is made, applicants must show that one of ordinary skill in the art would have known that this choice was intended.
29. In claim 17, the "where the aryl group contains at least one substituent" in the R^A definition makes no sense, since it already has to have either an alkyl or alkenyl substituent.
30. The term "acyl" (e.g. page 102, line 13) is indefinite. Does this embrace acids of S? P? As? What does the stem look like, i.e. if the acyl is e.g. RC(O), what is R?
31. Sulfonyl at page 102, line 13 (and page 119, line 3) makes no sense. Sulfonyl is the divalent -SO₂- radical, but is used for a monovalent moiety. Likewise sulfoxido (i.e. -S(O)-), sulfonate and sulfonamido.
32. Likewise "sulfate" on the next line is trivalent. Likewise in claim 36.
33. The intended scope of "Phosphorous containing moieties" is unclear. Could this include a cationic substituent which had a phosphate anion as a counterion, or an

anionic substituent (e.g. carboxylate) with a phosphonium cation as a counterion?

Would it include P atoms without functional groups, such as $-PO_2$ or phosphazene rings? Would it include highly reactive groups such as $-PCl_2$? The page 25 discussion is completely open-ended and does not discuss these issues.

34. The term "series II" on page 102, line 14 is undefined. These issues arise wherever R3 appears with definition.

35. Page 109, line 20 and many other places has "cyclic alkyl" which is impossible; alkyl cannot have a cycle. Correct is cycloalkyl.

36. A similar problem occurs for "cyclic alkene or alkenoxy" at e.g. page 113, line 18. The latter term is unclear additionally because it is not clear whether the oxygen atom in cyclic alkenoxy is or is not in the cycle.

37. Claims 11, 13, 15, and 17 lack a definition for R3.

38. Claim 36 contains a circular definition. R8 is defined in terms of R3 (page 118, lines 14-end of page), but R3 is defined (page 119, line 4) as Series II, which brings one back to R8 all over again. R8 is thus defined in terms of itself.

39. In addition, R8 is defined in terms of Series II, and the last item in that series has R8 in it, starting the definition all over again.

40. Claims 36-38 lack definitions for Y and R1.

41. Because of the first comma at page 114, line 5, it is unclear whether R3 is a choice for R^A or just a substituent on the aryl.

42. Claim 39 lacks a definition for R6.

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43. Claim 17 has ZR for the last choice for R^C. However, R is not defined. Elsewhere in the claim are 2 definitions for R, one in the definition of Z and one in the definition of R^D so it is unclear which, if any, of these is intended. Likewise claim 37-39.
44. Claim 36 has the same problem, and in addition has the problem where Y appears in the definition for R3.
45. Claim 17 contains no definition for the variable Y.
46. Claim 17 ends with a semicolon.
47. "Prodrug thereof" in claim 35 is indefinite. Determining whether a given derivative definitely is or is not a prodrug involves more than routine experimentation. If the derivative is active, open-ended experimentation may be involved to determine for sure whether the compound is a prodrug or whether it is active in its own right.
48. The material after the last comma in claim 17 says that each aryl or heteroaryl can be substituted or unsubstituted, but in the R^A definition, the text at page 114, line 5 specifically says that the aryl is substituted. It is not clear whether this last phrase in the claim is designed to override the line 5 text, and if so, why does the term "substituted" appear at line 5 if that is not truly what is required?
49. Claim 35 appears to be improperly dependent on claim 3. It appears that applicants intend the page 117, line 15 list to be used instead of the Series IIa or IIb lists of the listed claims, although the "in place of a substituent" is not entirely clear. But if so, the last 3 claim 35 choices are broader than claim 3 provides. Claim 3 has a G-linked group just in choice 2, which has the form P-M-P, which is much narrower than the two claim 35 terms. In addition, the first two terms are also somewhat broader than claim 3 provides --- note that e.g. the variable x does not appear in

claim 3. There may be dependency problems on the other claims as well, but it is impossible to tell because of the lack of variable definitions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
Art Unit 1624

July 10, 2002